

## **Medicare and Medicaid and Other Health Care Provisions of The Families First Coronavirus Response Act and The Coronavirus Aid, Relief, and Economic Security (CARES) Act**

### **Summary**

The Families First Coronavirus Response Act (Public Law 116-127) was signed into law on March 18, 2020. The Coronavirus Aid, Relief, and Economic Security Act or “CARES Act” (Public Law 116-136) was enacted into law shortly thereafter on March 27, 2020. This summary addresses those provisions in each Act that relate to the Medicare, Medicaid and Children’s Health Insurance Programs, the Public Health Service Act, and other provisions relating to certain health care programs of the Department of Health and Human Services (HHS).

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## **DIVISION H OF THE FAMILIES FIRST CORONAVIRUS RESPONSE ACT**

### **Sec. 6001. Coverage of Testing for COVID-19.**

Section 6001 requires group health plans and health insurance issuers in both the group and individual markets for health insurance to provide coverage without cost sharing or prior authorization during any portion of the COVID-19 emergency period for:

- Any in vitro diagnostic products used for the detection and diagnosis of COVID-19 including the cost of administering the products; and
- Any other items and services furnished to an individual during a visit for such testing (including the visit itself whether provided in-person or via telehealth).

This requirement applies to grandfathered as well as to self-insured employment-based health plans.

As initially enacted, covered products for the detection and diagnosis of COVID-19 required FDA approval. Under section 3201 of the CARES Act, Congress expanded the types of tests that could be used for COVID-19 to go beyond FDA approved tests to also include tests developed by states or the private sector. For a description of those tests, see section 3201 below.

### **Sec. 6002. Waiving Cost Sharing Under the Medicare Program for Certain Visits Relating to Testing for COVID-19.**

Section 6002 eliminates cost sharing under Medicare (Traditional Medicare and Medicare Advantage plans) for the provider or outpatient visit associated with the diagnosis of COVID-19 without any requirement to meet a deductible, beginning upon the enactment of the FFCRA. Payment will be 100 percent of the payment amount of the applicable outpatient payment system. A COVID-19 testing related service is a medical visit that:

- is a HCPCS evaluation & management (E/M) code used for (1) office and other outpatient services; (2) hospital observation services; (3) emergency department services; (4) nursing facility services; (5) domiciliary, rest home, or custodial care services; (5) home services; and (6) online digital E/M services;
- is furnished during any portion of the emergency period;
- results in an order for or administration of a clinical diagnostic laboratory test for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19; and
- relates to the furnishing or administration of the COVID-19 test or to the evaluation for determining the need for the test.

Applicable outpatient payment systems include the hospital outpatient prospective payment system, the physician fee schedule, the prospective payment system for federally qualified health

centers, the payment system for outpatient critical access hospital services, and payment system for rural health clinic services (as defined in section 1833(a)(3)). The Secretary will provide a modifier for use on claims to identify a specified COVID-19 testing related service. This provision may be implemented by program instruction or other sub-regulatory guidance.

### **Sec. 6003. Coverage of Testing for COVID-19 at no Cost Sharing Under the Medicare Advantage Program.**

Section 6003 adds laboratory testing for the detection of SARS-CoV-2 or the diagnosis of COVID-19 and testing related services to the list of Medicare Advantage (MA) benefits for which cost sharing charged to an enrollee cannot exceed the cost sharing required for those services under Parts A and B. Since section 6002 (see description above) eliminates cost sharing for these benefits under Parts A and B. MA plans may not impose cost sharing for:

- Any clinical diagnostic lab test administered during any portion of the COVID-19 emergency period for the detection of COVID-19 (including administration of the test or product); and
- Specified COVID-19 testing related services (as defined above in Sec. 6002.)

Plans may not apply prior authorization or other utilization management requirements with respect to such products or services during the COVID-19 emergency period.

The Secretary may implement this provision using program instruction or other sub-regulatory guidance. This section does not include a specific effective date and thus is effective on the date of enactment of the FFCRA.

### **Sec. 6004. Coverage at No Cost Sharing of COVID-19 Testing Under Medicaid and CHIP.**

#### Medicaid Coverage of COVID testing and related services

Beginning upon enactment of the FFCRA and extending for the duration of the COVID-19 emergency period, state Medicaid programs (including the District of Columbia and the Territories) are required to cover in-vitro diagnostic products for the detection of COVID-19 (including the costs of administering the products) and for related services. Related services include the patient's visit. Under the provision, covered individuals cannot be charged any cost sharing.

FFCRA defines the in vitro diagnostic products covered under this provision to be those used for the detection of the SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 that are approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act." An amendment to this section in Section 3717 of the CARES Act eliminates the phrase "that are approved, cleared, or authorized under section 510(k), 513, 515,

or 564 of the Federal Food, Drug, and Cosmetic Act.” See Section 3201 of the CARES Act (described below) for additional explanation.

#### State Option to extend Medicaid Coverage to Uninsured for COVID testing and related services

Section 6004 establishes an optional Medicaid eligibility coverage group for individuals who are uninsured. The coverage group is available upon enactment of the FFCRA and extends through the COVID-19 emergency period. Individuals who may be made eligible for the optional coverage group would qualify for a limited set of Medicaid benefits comprised only of in-vitro diagnostic products for the detection of COVID-19 (including the costs of administering the products) and for related services as defined for the mandatory benefit described above in section 6003. States are not permitted to charge covered individuals any cost sharing.

Section 3716 of the CARES Act clarifies that Medicaid beneficiaries who qualify for limited Medicaid benefits would be permitted to be covered under this option.

For states expanding Medicaid to uninsured individuals under this provision, the federal government would pay 100% of the costs of testing and related costs including the state’s administrative costs attributable to providing this coverage.

#### Processing of Applications

With respect to the new Medicaid COVID-19 eligibility category, section 6004 would require states to permit disproportionate share hospitals and federally qualified health centers to accept and conduct initial processing of applications for enrollment.

#### Children’s Health Insurance Program (CHIP) Coverage of COVID testing and related services

Beginning upon enactment of the FFCRA and extending for the duration of the COVID-19 emergency period, state CHIP programs (including the District of Columbia and the Territories) are required to cover in-vitro diagnostic products for the detection of COVID-19 (including the costs of administering the products) and related services. Related services include the patient’s visit. Covered individuals cannot be charged any cost sharing. CHIP programs are required to cover those products and services for both covered children as well as for targeted low-income pregnant women in states choosing to cover such women under their CHIP programs.

#### **Sec. 6005. Treatment of Personal Respiratory Protective Devices as Covered Countermeasures.**

Section 6005 adds personal respiratory protective devices as covered countermeasures for which temporary liability protections would apply. Under the provision, a covered person would be

immune from lawsuits and liability under federal and state laws with respect to all claims for loss caused by, arising out of, relating to, or resulting from the use by an individual of such a device used during the period beginning on January 27, 2020 and ending on October 1, 2024 in response to the COVID-19 emergency. The personal respiratory protective devices covered by this provision are those approved by the National Institute for Occupational Safety and Health and are subject to the emergency use authorization issued on March 2, 2020 or any subsequent emergency use authorizations during the COVID-19 outbreak.

Covered persons include the United States; manufacturers, distributors and program planners of covered countermeasures; qualified persons who prescribe, administer, or dispense such countermeasures, and officials, agents and employees of these persons.

#### **Sec. 6006. Application with Respect to Tricare, Coverage for Veterans, and Coverage for Federal Civilians.**

During the COVID-19 emergency period, TRICARE, the health care programs of the Department of Veterans Affairs, and health plans covering Federal Workers may not impose cost-sharing for testing for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (including the administration of those products) and the associated visit. Testing subject to this requirement is defined in section 6001 of the FFCRA (see above).

#### **Sec. 6007. Coverage of Testing for COVID-19 at No Cost Sharing for Indians Receiving Purchased/Referred Care.**

The Indian Health Service including an Urban Indian Organization may not impose cost-sharing for the testing for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 (including the administration of those products) for those receiving health services through the Indian Health Service. The testing services subject to this requirement are described in section 6001 of the FFCRA (see above).

#### **Sec. 6008. Temporary Increase of Medicaid FMAP.**

State and Territory Medicaid programs will receive a temporary 6.2 percentage point increase in their regular federal matching percentage applicable to most Medicaid benefits during the emergency period. The increased federal matching share would apply to Medicaid spending starting on the first day of the COVID-19 emergency period and extending to the last day of the calendar quarter in which the COVID-19 emergency period ends. It would apply to most Medicaid health care benefits. It would not apply to administrative costs nor to costs for ACA expansion adults.



States and Territories eligible to receive the enhanced matching rate during any calendar quarter must ensure that:

- Eligibility standards are no more restrictive and premiums no higher than those in place as of January 1, 2020;
- Continuous eligibility is available for enrollees through the end of the month of the emergency period unless an individual asks to be disenrolled or ceases to be a state resident; and
- The state covers testing services and treatment for COVID-19 without cost sharing including for vaccines, specialized equipment and therapies.

Sec. 3720 of the CARES Act (see below) amends section 6008 to permit states to receive the temporary FMAP increase for a period of 30 days beginning upon enactment even if premiums in place upon enactment are greater than those in effect on January 1, 2020. This would effectively provide the state with 30 days to come into compliance with this condition in order to continue receiving the temporary FMAP increase.

#### **Sec. 6009. Increase in Medicaid Allotments for Territories.**

Under section 6009, allotments for Territories for each of FY 2020 and 2021 are increased as follows:

<b>Territory</b>	<b>FFCRA Amounts</b>	<b>Prior Law Amounts</b>
Puerto Rico	2020: \$2,716,188,000 2021: \$2,809,063,000	2020: \$2,623,188,000 2021: \$2,719,072,000
Virgin Islands	2020: \$128,712,500 2021: \$127,937,500	2020 & 2021 \$126,000,000
Guam	2020: \$130,875,000 2021: \$129,712,500	2020 & 2021 \$127,000,000
Northern Mariana Islands	2020: \$63,100,000 2021: \$62,325,000	2020 & 2021 \$60,000,000
American Samoa	2020: \$86,325,000 2021: \$85,550,000	2020 & 2021 \$84,000,000

#### **Sec. 6010. Clarification relating to Secretarial Authority regarding Medicare Telehealth Services Furnished during COVID-19 Emergency Period.**

Section 6010 modifies an expansion made by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (CPRSAA; Public Law 116- ) of the Secretary's section 1135 emergency waiver authority. The CPRSAA gave CMS additional authority under section 1135 to waive certain restrictions of the Medicare telehealth benefit when provided to individuals by qualified providers. The term "qualified provider" was defined in the CPRSAA as



a physician or practitioner who furnished an individual an item or service through telehealth, certain to certain conditions. One condition was that the item or service was paid for under Medicare.

Section 6010 revises this condition to require that the item or service furnished to the individual would have been covered under the Medicare program if furnished to a Medicare beneficiary entitled to benefits under Part A, or enrolled in Part B, of the Medicare program.

## **CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY (CARES) ACT**

### **Title III-Supporting America’s Health Care System in the Fight Against the Coronavirus**

#### **Sec. 3001. Short Title.**

The short title for this title of the Act, the “Coronavirus Aid, Relief, and Economic Security Act,” is the same as the short title for the entire Act.

### **PART I – ADDRESSING SUPPLY SHORTAGES**

#### **Subpart A – Medical Product Supplies**

#### **Sec. 3101. National Academies Report on America’s Medical Product Supply Chain Security.**

Section 3101 requires the Secretary of Health and Human Services (HHS) to enter into an agreement with the National Academies of Sciences, Engineering, and Medicine (referred to as the “National Academies”) to report on the security of the U.S. medical product supply chain by May 26, 2020. The report will include:

- 1) An assessment and evaluation of the U.S. dependence on critical drugs and devices<sup>1</sup> that are sourced or manufactured outside of the U.S;
- 2) Recommendations to address any supply vulnerabilities or potential disruption of critical drugs and devices that would significantly pose a threat to public health or national security; and

The National Academies will consider input from Federal agencies and consult with relevant stakeholders with experience in health care and public health through public meetings and other forms of engagement.

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<sup>1</sup> Device and drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

### **Sec. 3102. Requiring the Strategic National Stockpile to Include Certain Types of Medical Supplies.**

Section 3102 amends Section 391-2(a)(1) of the Public Health Service (PHS) Act which requires the Secretary, in collaboration with the Assistant Secretary for Preparedness and Response (ASPR) and the Director of the Centers for Disease Control and Prevention (CDC) and in coordination with the Secretary of Homeland Security, to maintain a national stockpile of drugs, vaccines and other biological products, medical devices, and other supplies. Specifically, section 3102 adds personal protective equipment (PPE), ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests to the stockpile.

### **Sec. 3103. Treatment of Respiratory Protective Devices as Covered Countermeasures.**

Section 3103 amends Section 391-3(i)(1)(D) of the PHS Act which defines “covered countermeasures” that are immune from suit and liability under Federal and State law for all claims for losses caused by or related to the use of a covered countermeasure. Specifically, section 3103 adds a respiratory protective device to the list of countermeasures provided liability protection if the device is approved by the National Institute for Occupational Safety and Health and the Secretary determines it is a priority for use during a public health emergency.

## **Subpart B-Mitigating Emergency Drug Shortages**

### **Sec. 3111. Prioritize Reviews of Drug Applications; Incentives.**

Section 3111 amends section 506C(g) of the Federal Food, Drug, and Cosmetic (FD&C) Act to require the Secretary to expedite and prioritize the review of a drug, and expedite and prioritize an inspection or reinspection of a manufacturing site, when the Secretary concludes there is, or likely to be, a drug shortage.

### **Sec. 3112. Expansion to Include Active Pharmaceutical Ingredients.**

Section 3112 amends section 506C of the FD&C Act, which requires prescription drug manufacturers to notify the Food and Drug Administration (FDA) if they anticipate a permanent discontinuance or temporary interruption in the supply of a life-supporting or life-sustaining drug. Specifically, section 3112 adds both the requirement to report any drug that is critical to the public health during a declared public health emergency and the requirement to notify the Secretary of a permanent discontinuance or an interruption of an active pharmaceutical ingredient of a drug that is likely to lead to a disruption in the supply of the drug.

Notification includes information about both the active ingredient and alternative sources for the ingredient and any associated device used in the preparation or administration of the drug that contributes to the expected discontinuation or interruption of the manufacture of the drug. Manufacturers must also submit a contingency plan for any active ingredient or any associated medical device to ensure back-up supplies of drugs. When the manufacture of a drug is interrupted by missing or reduced supply of an active ingredient, the manufacturer must notify the FDA.

The Secretary must notify the Administrator the Centers for Medicare & Medicaid Services (CMS) of current drug shortages by September 23, 2020 and every 90 days thereafter.

### **Subpart C-Preventing Medical Device Shortages**

#### **Sec. 3121. Discontinuance or Interruption in the Production of Medical Devices.**

Section 3121 adds section 506J “Discontinuance or Interruption in the Production of Medical Devices” to Chapter V of the FD&C Act.<sup>2</sup> This provision requires manufacturers to notify the Secretary of a permanent discontinuance of a device (except for discontinuances resulting from a device modification) or an interruption of the manufacture of a device that is likely to lead to a meaningful disruption in the supply of the device and the reasons for the discontinuance or interruption.

Devices subject to this requirement include devices that (1) are life-supporting, life-sustaining, or intended for use in emergency medical care or surgery; (2) are critical to the public health during a public health emergency; and (3) the Secretary determines that information on potential supply disruptions of the device is needed during, or in advance of, a public health emergency. Notification is required at least 6 months before the date of the discontinuance or interruption, or as soon as practicable. If a manufacturer fails to meet the notification requirement, the Secretary must issue a letter to the manufacturer, and both the letter and the response will be posted on the FDA website.

The Secretary is required to distribute information about the devices to appropriate organizations including physicians, health providers, patient organizations, and supply chain partners. If the Secretary determines that disclosure would adversely affect the public health by increasing unnecessary purchases or other disruptions in the availability of the product, then the Secretary may choose not to make the information publicly available.

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<sup>2</sup> Nothing in the section affects the Secretary’s authority to expedite the review of devices under section 515 of the FD&C Act, section 515B of the FD&C Act relating to the priority review program for devices, and section 564 of the FD&C Act relating to the emergency use authorization authorities.

If the Secretary concludes there is, or is likely to be, a shortage of a device, the Secretary must prioritize and expedite review of devices<sup>3</sup> that could help mitigate or prevent such shortages or prioritize and expedite an inspection or reinspection of a manufacturing establishment that could help mitigate or prevent the device shortage.

The Secretary must establish and maintain an up-to-date list of devices determined to be in short supply. The list is required to be publicly available except if the Secretary determines the information would adversely affect the public health.

The term ‘meaningful disruption’ is defined as a change in production that is reasonably likely to lead to a reduction in the supply of a device by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product. The term does not include:

- 1) Interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time, not to exceed 6 months;
- 2) Interruptions in manufacturing of components or raw materials so long as such interruptions do not result in a shortage of the device and the manufacturer expects to resume operations in a reasonable period of time; and
- 3) Interruptions in manufacturing that do not lead to a reduction in procedures or diagnostic tests associated with a medical device designed to perform more than one procedure or diagnostic test.

The term ‘shortage’ of a device means a period of time when the demand or projected demand for the device within the U.S. exceeds the supply of the device.

## **PART II – ACCESS TO HEALTH CARE FOR COVID-19 PATIENTS**

### **Subpart A – Coverage of Testing and Preventive Services**

#### **Sec. 3201. Coverage of Diagnostic Testing for COVID-19.**

Section 6001(a) of division F of the Families First Coronavirus Response Act (FFCRA) requires group health plans and health insurance issuers in both group and individual markets for health insurance to provide coverage, without cost sharing or prior authorization, during any portion of the COVID-19 emergency period for any in vitro diagnostic products used for the detection and diagnosis of COVID-19. It defined in vitro diagnostic products are those products approved, cleared, or authorized by the FDA under section 510(k), 513, 515 or 564 of the FD&C Act.

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<sup>3</sup> Devices submitted under sections 513(f)(2), 515, 510(k) or 520(m) of the FD&C Act.

Section 3201 amends this provision of the FFCRA to expand the definition of an in vitro diagnostic test for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 to include unapproved tests pursuant to the FDA's emergency use authorization. Under this authority, the FDA may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions. Additionally, tests developed in and authorized by a State that has notified the FDA of its intention to review tests intended to diagnose COVID-19 are included. Finally, the Secretary has authority to include such others tests it determines to be appropriate; it would do so though guidance.

### **Sec. 3202. Pricing of Diagnostic Testing.**

Section 3202(a) requires a group health plan or health insurance issuer to reimburse a provider of a diagnostic test for COVID-19 by (1) either the negotiated rate the health plan or issuer had in effect before the declaration of the public health emergency or (2) if the health plan or issuer does not have a negotiated rate with the provider, an amount equals to the price for the service listed by the provider on a public website or a negotiated rate that is less than the listed price.

Section 3202(b) requires each provider of a COVID-19 diagnostic test to list the price for the test on the provider's public website. The Secretary may impose a civil monetary penalty on any provider that fails to post this information during the public health emergency period.

### **Sec. 3203. Rapid Coverage of Preventive Services and Vaccines for Coronavirus.**

Section 3203 requires group health plans and health insurance issuers offering group or individual health insurance to cover, without cost-sharing, any qualifying coronavirus preventive service. A qualifying coronavirus preventive service means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease and is:

- An evidence-based item or service for which the United States Preventive Service Task Force has recommended an "A" or "B" rating; or
- An immunization recommended from the Advisory Committee on Immunization Practices of the CDC.

This requirement takes effect 15 business days after the date the recommendation is made.

## **Subpart B—Support for Health Care Providers**

### **Sec. 3211. Supplemental Awards for Health Centers.**

Appropriates \$1.32 billion in additional FY 2020 funding for supplemental awards for improving quality of care under section 330(d) of the PHS Act to health centers for the detection of SARS-CoV-2 or the prevention, diagnosis and treatment of COVID-19. These appropriated amounts are subject to the conditions initially set forth in the Department of Defense and Labor, Health and

Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2015 (P.L. 115-245) and continued in the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), pertaining to limits on use of funds for defense of malpractice and negligence suits and targeting of funds to support and enhance behavioral health, mental health, and substance use disorder services.

#### **Sec. 3212. Telehealth Network and Telehealth Resource Centers Grant Programs.**

The telehealth network grant program under section 330I of the PHS Act is reauthorized and modified to direct funds to evidence-based projects that utilize telehealth technology through telehealth networks to (1) expand access to, coordinate, and improve access to and the quality of health care services, and (2) expand and improve the quality of health information available to providers, patients and families. (This language replaces a focus on demonstration of how telehealth technology can be used in rural, frontier and medically underserved areas; the additional purpose of training health care providers is removed.)

Eligibility for telehealth network grants or telehealth resource center grants is no longer limited to nonprofit entities. Grants may be awarded for a period of up to 5 years instead of 4 years. In addition to existing requirements, the grant application must include a description of how the project will improve access to and quality of services for populations served as well as how it will meet the populations' health care needs. Substance use disorder providers and facilities are recognized along with mental health services providers and facilities. Preference for telehealth network grants is given to proposals that promote regional as well as local connectivity; the preference regarding integration of health care information is removed. A record of success in providing telehealth services to rural areas as well as medically underserved areas and populations is recognized in awarding telehealth resource center grants. The requirement that at least half the telehealth network grant funds are awarded for projects in rural areas is retained. Among the permitted uses of telehealth resource center grant funds is use of telehealth to provide health care information and education for consumers more effectively, replacing use for providing such information and education to both providers and consumers. An entity receiving either type of grant may not use more than 20 percent of total grant funds to purchase or lease equipment; this replaces a 40 percent limit. Numerous technical and wording changes are made to section 330I.

For each of fiscal years 2021 through 2025, \$29 million is authorized to be appropriated for these programs.

The Secretary is directed to report to the Senate Committee on Health, Education, Labor, and Pensions (HELP) and the House Committee on Energy and Commerce on the activities and outcomes of these grant programs. The first report is due 4 years after enactment of the CARES Act and subsequent reports every 5 years thereafter.

### **Sec. 3213. Rural Health Care Services Outreach, Rural Health Network Development, and Small Health Care Provider Quality Improvement Grant Programs.**

The rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs under section 330A of the PHS Act are reauthorized, with modifications. The general purpose of these grant programs to expand access to, coordinate, and improve the quality of essential health services and enhance the delivery of health care in rural areas is amended to refer to basic health services instead of essential health services. For each of the three programs, grants will be available for up to 5 years instead of 3 years. In awarding grants the Secretary is now directed to give specified preferences “as appropriate.” Technical changes are made to section 330A.

The awarding of rural health care services outreach grants is modified to state that grants may be awarded for improving and expanding health care delivery to include new and enhanced services in rural areas “through community engagement and evidence-based or innovative, evidence-informed models.” Instead of a description of how the local community or region will be involved in development and operations of the project, the application now requires a description of the involvement of rural underserved populations in the local community or region.

Rural health network development grants are to be awarded to eligible entities to plan, develop and implement integrated health care networks that collaborate in order to achieve the specified program goals. Instead of describing how the local community will benefit from and be involved in the network’s activities and how it will experience increased access to quality health care services across the continuum of care as a result of the integration activities of the network, the application must describe these benefits, involvement and outcomes with respect to rural underserved populations in the local community or region.

For both the rural health care service outreach and rural health network development programs, grants are no longer restricted to public or nonprofit rural entities but instead eligibility requires the entity to have demonstrated experience serving, or the capacity to serve, rural underserved populations.

Quality improvement activities for purposes of the small health care provider quality improvement grant program are identified to include activities related to increasing care coordination, enhancing chronic disease management, and improving patient health outcomes. Eligible entities will include a rural provider or network of small rural providers identified by the Secretary as a key source of local *or regional* care. Applications must include a description of how rural underserved populations in the local community or region will experience increased access to quality health care services across the continuum of care as a result of the proposed activities.



A total of \$79,500,000 for each of fiscal years 2021 through 2025 is authorized to be appropriated for these three programs.

#### **Sec. 3214. United States Public Health Service Modernization.**

Amendments are made in sections 203 and 203A of the PHS Act to clarify references to the Ready Reserve Corps, which provides for additional Commissioned Corps personnel to be available on short notice to assist regular Commissioned Corps personnel during public health or national emergencies. Section 211 of the PHS Act (including provisions for voluntary retirement of Commissioned Corps members at age 64; authority of the Secretary to retire Corps members who have attained specified years of active service; and authority for involuntary recall of retirees to active duty) is amended to clarify its application to the Regular Corps and not the Ready Reserve Corps.

Certain provisions applicable to the Armed Forces (Title 10 of the US Code) are extended to the Commissioned Corps: Chapter 1223, Retired Pay for Non-Regular Service; Section 12601, Compensation: Reserve on active duty accepting from any person; and Section 12684, Reserves: separation for absence without authority or sentence to imprisonment.

#### **Sec. 3215. Limitation on Liability for Volunteer Health Care Professionals During COVID-19 Emergency Response.**

This section provides that health care professionals are not liable under state or federal law for any harm cause by an act or omission while providing health care services with respect to COVID-19 during the COVID-19 public health emergency if (1) the professional is providing those services as a volunteer and (2) the act or omission occurs in the course of providing health care services; in the professional's capacity as a volunteer; and in the course of providing health care services that are within the scope of the volunteer's state license, registration or certification or that do not exceed the scope of such license, registration or certification; and (3) the act or omission occurs in a good faith belief that the individual being treated is in need of health care services.

The health care services involved are those that relate to the diagnosis, prevention, or treatment of COVID-19 or to the assessment or care of an individual related to an actual or suspected case of COVID-19. Services are provided as a volunteer if the health care professional does not receive compensation or anything of value for the services (i.e., insurance payment) excluding receipt of items to be used exclusively for providing health services as a volunteer and reimbursement for travel. Payment in cash or kind for room and board is also excluded if the services are rendered more than 75 miles from the volunteer's principal residence.

This provision does not apply if the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual who was harmed by the health care professional; or if the health care professional rendered the services under the influence of alcohol or an intoxicating drug, as determined by state law.

State laws or those of a political subdivision of a state are pre-empted to the extent they are inconsistent with this section, unless they provide greater protection from liability. These protections are in addition to those provided under the Volunteer Protection Act of 1997 (P.L. 105-19) and are effective upon enactment of the CARES Act and only during the public health emergency declared on January 31, 2020 with respect to COVID-19.

#### **Sec. 3216. Flexibility for Members of National Health Service Corps During Emergency Period.**

During the COVID-19 public health emergency declared on January 31, 2020, the Secretary may assign members of the National Health Service Corps to provide health services in places and for times the Secretary determines necessary to respond to the emergency. The assignments are to be made with the voluntary agreement of the Corps members; the places to which they are assigned must be within a reasonable distance from the original assignment site; and the total number of hours required of Corps members is to be the same as the hours required prior to the emergency.

### **Subpart C—Miscellaneous Provisions**

#### **Sec. 3221. Confidentiality and Disclosure of Records Relating to Substance Use Disorder.**

Section 543 of the PHS Act establishes rules for the confidentiality and privacy of medical records of individuals receiving substance use disorder services under a federal program. The regulations implementing this provision are referred to as the Part 2 regulations (42 CFR Part 2). Prior to the CARES Act, section 543 only permitted the disclosure of such records under limited circumstances and purposes. The CARES Act makes a number of changes to section 543.

The section on consent is modified to specify that both use and disclosure of the contents of the medical record are available with the prior written consent of the patient involved. It further specifies types of uses and disclosures for which protection is provided (i.e., by a covered entity, business associate or a federal program for treatment, payment and health care operations under the HIPAA regulations). It permits such prior written consent to apply to all future uses and disclosures until consent is revoked by the patient. Additionally, a covered entity must comply with a patient's request that the covered entity restrict disclosure of the contents of a medical record disclosure where, except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of

carrying out treatment); and the protected health information pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full.<sup>4</sup>

Before the enactment of the CARES Act, section 543 specified three circumstances under which the content of a patient's medical record otherwise protected under this section may be made available without the patient's prior written consent, such as to medical personnel for a bona fide medical emergency. The CARES Act adds a fourth: disclosure to a public health authority as long as the disclosure meets requirements for de-identified information under section 164.514(b) of title 45, Code of Federal Regulations (or successor regulations).

The CARES Act revises the rules for use of these records in criminal proceedings. The first change is that the rules for use are expanded in the statute to apply in civil or administrative proceedings. Another modification clarifies that a patient may provide consent to use the protected content in a criminal, civil or administrative proceeding; previously, the statute only specified that such access was available upon a court order. Additionally, the protections, and the authority to waive those protections, also apply to testimony relaying the information contained in the protected medical record. The revisions also clarify that these rules apply in the context of federal, state or local authorities.

Section 543 was also modified to provide specific details for how the records or testimony are to be treated. They may **not** (i) be entered into evidence in any criminal prosecution or civil action before a Federal or State court; (ii) form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency; (iii) be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation; and (iv) be used in any application for a warrant.

Terminology added to section 543 by the CARES Act, such as covered entity, business associate, breach, treatment, payment, and health care operations, among others, are defined in the context of the HIPAA regulations, and the meanings that apply to those terms under HIPAA apply to section 543 and the Part 2 regulations.

An antidiscrimination provision is codified in section 543. If an entity receives an individual's medical record protected under section 543, or information in that medical record, pursuant to an inadvertent or intentional disclosure, that entity may not discriminate against the individual with respect to the following:

- Admission, access to, or treatment for health care;
- Hiring, firing, or terms of employment, or receipt of worker's compensation;
- The sale, rental, or continued rental of housing;
- Access to Federal, State, or local courts; or

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<sup>4</sup> See section 13405(a) of the Health Information Technology and Clinical Health Act (42 U.S.C. 17935(a)).

- Access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.

The term “entity” is not defined. Additionally, it prohibits providers of substance use disorder programs that receive federal funding (i.e., programs conducted, regulated, or directly or indirectly assisted by any department or agency of the United States) to discriminate against individuals using medical records, or information in those records, inadvertently or intentionally disclosed in providing access to services under those programs.

In the case of a breach of by a covered entity of a medical record, or information in that medical record, the covered entity must follow the same requirements and process for notification of that breach as is required under section 13402 of the HITECH Act (42 U.S.C. 17932).

The CARES Act also changes the mechanism by which penalties may be imposed on persons who violate section 543. Instead of penalties under title 18 of the United States Code, relating to criminal penalties under federal law generally, penalties will be imposed under the HIPAA simplification enforcement mechanism under Part C of title XI of the Social Security Act, specifically sections 1176 and 1177 (42 U.S.C. 1320d–5, 1320d–6).

The effective date for all the changes is 12 months after the date of enactment of the CARES Act. HHS must coordinate with other departments to update the Part 2 regulations by that deadline. Additionally, within that same timeframe, HHS must update regulations under section 164.520 of title 45, CFR, for notice requirements for covered entities and other entities creating or maintaining the records to accommodate the changes to section 543 of the PHS Act. The affected notice requirements include the statement of the patient’s rights with respect to protected health information and a brief description of how to exercise those rights, and a description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient’s written authorization.

Section 3221 of the CARES Act also includes several rules of construction to guide the implementation and interpretation of section 543 of the PHS Act as modified. Specifically, nothing shall be construed to limit either (i) a patient’s right to request a restriction on the use or disclosure of a medical record under 543(a) for purposes of treatment, payment, or health care operations; or (ii) a covered entity’s choice to obtain the consent of the individual to use or disclose such medical record to carry out treatment, payment, or health care operations.

Finally, section 3221 contains a Sense of the Congress provision that, while not legally binding, provides insight into congressional intent behind this enactment.

## **Sec. 3222. Nutrition Services.**

Nutrition services transfer criteria. During the period of the COVID-19 public health emergency, the Secretary is required to allow a state agency or an area agency on aging, without prior approval, to transfer up to 100 percent of the funds it receives under the Older Americans Act (OAA) for congregate nutrition services (Subpart 1 of Part C of the OAA) and home delivered nutrition services (subpart 2 of Part C) between these programs, for such use as the state agency or area agency on aging considers appropriate to meet the needs of the state or area served.

Home-delivered nutrition services waiver. During the period of the COVID-19 public health emergency, an individual who is unable to obtain nutrition because they are practicing social distancing will be treated as an individual who is homebound by reason of illness, for purposes of determining the home delivery of nutrition services under the OAA.

Dietary guidelines waiver. During the COVID-19 public health emergency, the Assistant Secretary may waive the requirement that meals provided under the congregate nutrition services and home delivered nutrition services programs meet the dietary guidelines specified under section 339(2)(A)(i) and (ii) of the OAA.

## **Sec. 3223. Continuity of Service and Opportunities for Participants in Community Service Activities under Title V of the Older Americans Act of 1965.**

The Secretary of Labor is given certain authorities to ensure continuity of services to individuals participating in community services activities under title V of the OAA. Specifically, the Secretary may take any of the following steps if she determines it is appropriate to do so because of the effects of the COVID-19 public health emergency:

- Allow individuals participating in title V project as of March 1, 2020 to extend their participation period beyond the program's applicable participation limits;
- Increase the average participation cap for eligible individuals applicable to grantees; and
- Increase the amount available to pay the authorized administrative costs for a project by as much as 20 percent of the grant amount.

## **Sec. 3224. Guidance on Protected Health Information.**

Not later than 180 days after the date of enactment of the CARES Act, the HHS Secretary shall issue guidance on the sharing of patients' protected health information during the COVID-19 public health emergency and the COVID-19 related emergencies declared by the President under the Disaster Relief and Emergency Assistance Act and the National Emergencies Act. The guidelines must include information on compliance with regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA) and applicable policies, including those that take effect during the emergencies.

## **Sec. 3225. Reauthorization of Healthy Start Program.**

The Healthy Start for Infants grant program is reauthorized with modifications. Considerations in making grants are amended to include communities with high rates of infant mortality or poor perinatal outcomes generally or in specific populations; factors contributing to infant mortality including poor birth outcomes (such as low birthweight and preterm birth) and social determinants of health; collaboration with the local community in developing the project; and the grantee (or potential grantee's) use and collection of data to demonstrate its effectiveness in decreasing infant mortality and improving birth outcomes. The Secretary is directed to ensure coordination of the Healthy Start program with other HHS-supported programs and activities related to reducing infant mortality and improving perinatal and infant health outcomes.

In addition to current requirements, program evaluations conducted by the Secretary may include, to the extent practicable, include information on: (1) progress toward achieving any grant metrics or outcomes related to reducing infant mortality, improving perinatal outcomes, or reducing health disparities; (2) recommendations on improvements that may assist with addressing gaps, and (3) the extent to which the grantee coordinated with the local community in development of the project and delivery of services, including with respect to technical assistance and mentorship programs.

The GAO is directed to conduct an independent evaluation of the Healthy Start program and report to the appropriate committees of Congress no later than 4 years after the date of enactment of the CARES Act. GAO is to consider the information from the Secretary's evaluations, and its report is to include: (1) assessments and recommendations regarding the allocation of Healthy Start program grants by the Health Resources and Services Administration (HRSA), including considerations made regarding disparities in infant mortality or perinatal outcomes among urban and rural areas in making grant awards; (2) progress made toward reducing infant mortality, improving perinatal outcomes, and impacting racial and ethnic disparities in these outcomes; (3) the ability of grantees to improve health outcomes, promote awareness of Healthy Start program services, incorporate and promote family participation, facilitate coordination with the local community, and increase grantee accountability through quality improvement, performance monitoring, and evaluation and the effect of these metrics on decreasing infant mortality and improving perinatal outcomes, and (4) the extent to which federal programs are coordinated across agencies and the identification of opportunities for improved coordination.

Funding is authorized at \$125.5 million annually for fiscal years 2021 through 2025.

### **Sec. 3226. Importance of the Blood Supply.**

The Secretary of HHS is directed to conduct a national campaign to improve public and health care provider awareness of the importance and safety of blood donation and the need for donations for the blood supply during the COVID-19 public health emergency. For this purpose, the Secretary may contract with one or more public or nonprofit entities. The national blood donation awareness campaign may include television, radio, internet and newspaper public service announcements and other activities to provide for public and professional awareness and education. The Secretary shall consult with the FDA Commissioner, the Assistant Secretary of Health, the Directors of the CDC, the NIH, and heads of other relevant federal agencies, accrediting bodies and representative organizations.

Not later than 2 years after enactment of the CARES Act, the Secretary must report to the Senate HELP and House Energy and Commerce committees on the activities carried out in this section, trends in the blood supply, and an evaluation of the impact of the public awareness campaign, including any geographic or population variations.

## **PART III—INNOVATION**

### **Sec. 3301. Removing the Cap on OTA During Public Health Emergencies.**

The Biomedical Advanced Research and Development Authority (BARDA), established under section 319L of the PHS Act, is part of the HHS Office of the Assistant Secretary for Preparedness and Response. BARDA works in partnership with industry to support the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile.

Under section 319L of the PHS Act, BARDA has authority to enter into transactions other than procurement contracts, grants, and cooperative agreements. One limitation on this authority is that if a project is expected to cost HHS more than \$100 million, a written determination must be provided by the Assistant Secretary for Financial Resources indicating that the use of the “other transactions” authority is essential to promoting the success of the project.

Section 3301 provides that projects carried out under BARDA for purposes of a public health emergency declared by the Secretary under section 319 are not subject to the dollar cap provision. When entering into transactions for such projects the Secretary is directed to use competitive procedures to the maximum extent possible. Transactions entered into during a public health emergency shall not be terminated before the terms of the agreement are completed solely because the emergency ends. After a public health emergency expires the Secretary is required to report to the Senate HELP and House Energy and Commerce committees regarding



the use of the this authority, including any outcomes, benefits, and risks associated with the use of the funds and a description of the reasons why the authority was used for the project(s).

### **Sec. 3302. Priority Zoonotic Animal Drugs.**

Chapter V of the Federal Food, Drug, and Cosmetic Act is amended to provide for expedited development and review of new animal drugs that alone or in combination with other animal drugs have the potential to prevent or treat a zoonotic disease in animals, including a vector-borne disease that has the potential to cause serious adverse health consequences or life-threatening diseases in humans.

The Secretary has 60 days to determine whether a request for designation as a priority zoonotic animal drug meets these criteria. Actions to expedite the development and review of an application for approval or conditional approval of a priority zoonotic animal drug may include, as appropriate: (1) steps to ensure efficient, scientifically appropriate design of clinical trials, such as by use of novel trial designs or drug development tools, including biomarkers, that may reduce the number of animals needed for studies; (2) providing timely advice and interactive communication with the sponsor to ensure that the development program to gather the nonclinical and clinical data needed for approval is as efficient as possible; (3) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including across agency centers; and (4) implementing additional administrative or process enhancements to facilitate an efficient review and development program.

## **Part IV—Health Care Workforce**

### **Sec. 3401. Reauthorization of Health Professions Workforce Programs.**

Section 3401 reauthorizes many provisions of title VII of the PHS Act relating to training programs for various health professions and includes some additional changes as follows:

- Section 736 (relating to centers of excellence in health professions education for under-represented minority individuals): authorizes appropriations of \$23,711,000 for each of fiscal years (FY) 2021 through 2025.
- Section 737 (relating to scholarships for disadvantaged students): authorizes appropriations of \$51,470,000 for each of fiscal years 2021 through 2025.
- Section 738 (relating to loan repayments and fellowships for faculty position): authorizes appropriations of \$1,190,000 for each of fiscal years 2021 through 2025.
- Section 739 (relating to educational assistance in health professions regarding individuals for disadvantaged backgrounds): authorizes appropriations of \$15,000,000 for each of fiscal years 2021 through 2025.

Reporting requirements for programs under section 737, 738, and 739 are changed to once every five years, beginning with September 30, 2025.

- Section 747 (relating to primary care training and enhancement):
  - Authorizes appropriations of \$48,924,000 for each of fiscal years 2021 through 2025;
  - Modifies the existing authority for training under a demonstration program for patient-centered medical homes to focus on innovative models of providing care, and professional training under those models, in the context of patient-centered medical homes; and
  - Permits the Secretary to give priority to programs in rural areas, including Tribes or Tribal organizations operating programs in rural areas.
- Section 748 (relating to dentistry training): authorizes appropriations of \$28,531,000 for each of fiscal years 2021 through 2025.
- Section 751 (relating to area health education centers): authorizes appropriations of \$41,250,000 for each of fiscal years 2021 through 2025.
- Section 754 (relating to the Quentin N. Burdick program for rural interdisciplinary training): modifies the design requirements for interdisciplinary training project funding to permit innovative or evidence-based designs.
- Section 755 (relating to allied health and other disciplines): permits funding for activities for health professions in maternal and child health.
- Section 761 (relating to health professions workforce information and analysis): authorizes appropriations of \$5,663,000 for each of fiscal years 2021 through 2025.
- Section 762 (relating to the Advisory Council on Graduate Medical Education):
  - Designates the HRSA Administrator as a member of the Council;
  - Eliminates the statutory termination date of the Council;
  - Revises reporting requirements; reports due every 5 years, beginning with September 30, 2023.
- Section 766 (relating to public health training centers): updates the goals of training centers to omit references to 2000 HHS goals and to focus on projects to improve preventive medicine, health promotion and disease prevention, or access to and quality of health care services in rural or medically underserved communities.
- Section 770 (relating to authorization of appropriations of public health workforce programs, including section 766 described above): authorizes appropriations of \$17,000,000 for each of fiscal years 2021 through 2025.
- Section 775 (relating to the pediatric specialty loan repayment program): strikes references to specific authorization amounts and instead authorizes appropriations of such sums as may be necessary for each of fiscal years 2021 through 2025.

### **Sec. 3402. Health Workforce Coordination.**

By March 27, 2021, the Secretary must develop a comprehensive and coordinated plan for health care workforce development programs carried out by the Department. This must be done in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Council on Graduate Medical Education.

Under the plan, the Secretary must assess the extent to which these programs are strengthening the health care system, identify gaps in meeting healthcare workforce goals identified by HRSA, identify actions to meet those goals as well as any barriers to implementing those actions.

The Secretary must also coordinate with other federal departments that administer workforce development programs, improve the quality and consistency of information collected through those programs, and implement improvements.

By March 27, 2022, a report is due to Congress to describe the plan and actions taken to implement it.

### **Sec. 3403. Education and Training Relating to Geriatrics.**

The CARES Act rewrites section 753 of the PHS Act and makes a number of substantive changes to the programs for geriatric training and education. The revised program consists of two components: geriatric workforce enhancement programs and geriatric academic career awards. The revised text of section 753 appears to consolidate various activities previously included in the law, to expand the types of entities eligible for grants, and to omit a number of details or specific requirements previously included in the statute.

#### *Geriatric Workforce Enhancement Programs*

In addition to entities previously eligible to operate geriatric education centers, other entities that are eligible for grants, awards or cooperative agreements to establish or operate a geriatric workforce enhancement program include nursing schools, health care facilities, programs for certification as a certified nurse assistant, partnerships of such schools and facilities or of such programs and facilities, and other health professions schools or programs approved by the Secretary.

Geriatric workforce enhancement programs must support the training of health professionals in geriatrics, including traineeships or fellowships, and emphasize patient and family engagement, integration of geriatrics with primary care and other appropriate specialties, and collaboration with community partners. Activities may include clinical training on integration of geriatric and primary care services, interprofessional training, training-related community-based programs, and education on Alzheimer's disease for families and caregivers as well as health care workers.

Grants may not be longer than 5 years. In making awards, the Secretary must prioritize programs that coordinate with other federal or state programs or another public or private entity and must give priority to applicants that serve rural or medically underserved areas. Priority may be given to programs that integrate geriatrics in primary care practice or other specialties; that support training or retraining of faculty, primary care providers and other direct care providers; that emphasize education and engagement of family caregivers; or that conduct outreach to communities with a shortage of geriatric workforce professionals. The Secretary may provide additional support for activities in areas of demonstrated need, such as education and training for home health workers or family caregivers.

Entities must submit annual reports to the Secretary, and the Secretary must submit reports to Congress every 5 years, with the first report due March 27, 2024.

#### *Geriatric Academic Career Awards*

Programs for geriatric academic careers awards are expanded to include the career development of academic geriatric health professionals as well as academic geriatricians. The types of entities eligible to apply for awards on behalf of eligible individuals is expanded to include other accredited health professions schools or graduate programs approved by the Secretary.

Individuals are eligible for a career award if they have a junior, nontenured, faculty appointment at an accredited health professions school or graduate program in geriatrics or a geriatrics health profession and meet one of the following requirements:

- They are employed in an accredited health professions school or graduate program approved by the Secretary who are board certified or board eligible (or have completed required training) in internal medicine, family practice, psychiatry, or licensed dentistry.
- They have completed an approved geriatric fellowship or certain specialty training in geriatrics.

An individual promoted during the period of the award continues to be treated as eligible for the period of the award. Individuals must spend at least 75 percent of their time supported by the award on teaching or developing skills in interdisciplinary geriatric education and meet a service requirement. The service requirement involves training in clinical geriatrics, including interprofessional teams; the training must constitute at least 75 percent of the obligations under the award.

Awards may be made for up to 5 years. For physicians, awards shall be at least \$75,000 in fiscal year 2021. The amount for subsequent fiscal years is increased by the consumer price index. The Secretary shall set award amounts for non-physicians. The Secretary must seek to ensure an equitable geographic distribution among award recipients, including in rural and medically underserved areas.

For both programs, in making awards under section 753, the Secretary is not required to provide preferences for entities that have a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; that during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings; or that uses a longitudinal evaluation under section 761(d)(2) of the PHS Act and reports data from such system to the national workforce database.

Appropriations of \$40,737,000 are authorized for each of fiscal years 2021 through 2025.

#### **Sec. 3404. Nursing Workforce Development.**

Section 3404 amends many provisions of title VIII of the PHS Act (relating to nursing workforce development programs).

For purposes of title VIII programs generally, the CARES Act adds a nurse managed health clinic to the types of entities eligible for awards, grants or cooperative agreements for nursing workforce development programs. It is defined as “a nurse practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.”

##### *General Application Requirements (Section 802)*

An application required for a program must include performance outcome standards that address relevant national nursing needs that the program will address. The CARES Act amends section 802(c) to also require that those standards address how the project aligns with requirements to address challenges related to the distribution of the nursing workforce, increase access to and quality of health care services, and address strategic goals and priorities identified by HHS (under section 806(a) of the PHS Act as amended by the CARES Act and described below).

##### *Use of Funds (Section 803)*

The CARES Act amends section 803(b) maintenance of effort requirements to clarify that federal funding is intended to supplement, not supplant, existing non-federal expenditures for program activities.

##### *Generally Applicable Provisions (Section 806)*

The CARES Act amends section 806(a) to further specify that projects and activities under title VIII of the PHS Act are intended to address national nursing needs, including the following:

- Challenges related to the distribution of the nursing workforce, through education and training of nursing students to address areas with nursing shortages;
- Increasing access to and quality of health care services, including through training of registered nurses (RNs), advance practice registered nurses (APRNs) and advanced education nurses; and
- Strategic goals and priorities identified by the Secretary consistent with title VIII.

Under section 802(b)(2), continued funding for a program or project is conditioned on demonstration that satisfactory progress is being made in meeting the objectives. This is modified to specify data and information must be reported to demonstrate that the program or project is meeting the performance outcome standards included in the application (described above for section 802).

Section 802(e) is amended to clarify that a peer group reviewing a grant application must have relevant expertise and experience.

A biennial reporting requirement to Congress is added. Each report must include information on the extent to which programs and activities under title VIII meet the relevant goals and performance measures, and the extent to which HHS coordinates with other Federal departments on programs designed to improve the nursing workforce.

#### *Advanced Education Nursing Grants (Section 811)*

The CARES Act adds clinical nurse specialist programs to the list of nursing programs for which grants are mentioned in the statutory text of section 811 and specifies requirements for those programs. These clinical nurse specialist education programs must have as their objective the education of clinical nurse specialists who will, upon completion of the program, be qualified to effectively provide care through the wellness and illness continuum to inpatients and outpatients experiencing acute and chronic illness.

The definition of advanced education nurses is also modified to include clinical nurse leaders and to refer to “R.N./graduate degree programs” in lieu of “R.N./Master’s degree programs”.

#### *Nurse Education, Practice, and Quality Grants (Section 831)*

The grant program under section 831 is modified in the heading to include a reference to retention grants; the nursing retention grant program under section 831A is removed from the statute. Language relating to the development and implementation of internships and residency programs under section 831A is expanded upon and added to section 831.

Other changes to section 831 include expanding in the statute the types of personnel for whom career advancement may be provided through such grants, such as diploma degree or associate degree nurses, and other health professionals, such as health aides or community health practitioners certified under the Community Health Aide Program of the Indian Health Service. Additionally, the practice priority areas for training are expanded to include care of individuals with mental illness. The types of entities eligible for grants are expanded to include federally qualified health centers and nurse-managed health clinics (as defined above).

The CARES Act removes requirements for preferences for grants for retention priority areas identified in 831(c) and for education in new technologies (including distance learning methodologies) under section 831(a)(2). It also strikes the authorization of appropriations contained in section 831; the funding amounts for these grants are specified in section 871.

The requirement for congressional reports for these programs is now included in the general reporting requirements for title VIII programs under section 806 of the PHS Act.

#### *Loan Repayment and Scholarship Programs (Section 846)*

The CARES Act eliminates a limitation under section 846 that prohibited the assignment of a nurse who received assistance under a title VIII loan or scholarship program to be assigned to any private entity unless that entity is nonprofit.

It also strikes the authorization of appropriations contained in section 846(i); the funding amounts for these programs are specified in section 871.

#### *Nurse Faculty Loan Program (Section 846A)*

The authorization of appropriations contained in section 846A(f) is struck; the funding amounts for this program is specified in section 871.

#### *Eligible Individual Student Loan Repayment (Section 847)*

The authorization of appropriations contained in section 847(g) is struck; the funding amounts for this program are specified in section 871.

#### *National Advisory Council on Nurse Education and Practice (Section 851)*

The CARES Act adds clinical nurse specialists to the list of advanced education nursing groups who may be represented on the Council. It also modifies the sources of funding from which amounts may be used to support nurse education and practice activities of the Council; the scope is narrowed from all of title VIII to parts B, C and D of that title.



### *Public Service Announcements (Part G)*

The CARES Act strikes sections 861 (relating to public service announcements) and section 862 (relating to grants for state and local public service announcements).

### *Funding (Section 871)*

The CARES Act authorizes the following appropriations for each of fiscal years 2021 through 2025:

- \$137,837,000 to carry out parts B, C, and D, relating to grant programs and activities of the National Advisory Council on Nurse Education and Practice; and
- \$117,135,000 to carry out part E, relating to student loan programs.

## **Subtitle B—Education Provisions**

This subtitle is entitled the “COVID–19 Pandemic Education Relief Act of 2020.” It provides relief under a number of authorities of the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.). This summary does not include any description of these education policy changes.

## **Subtitle C—Labor Provisions**

This subtitle amends a number of federal labor laws, including the Family and Medical Leave Act of 1993, the Emergency Paid Sick Leave Act (contained in division E of the Families First Coronavirus Response Act), the Emergency Unemployment Insurance Stabilization and Access Act of 2020, the Internal Revenue Code of 1986, and other laws. This summary does not include any description of these labor law policy changes.

## **Subtitle D—Finance Committee**

### **Sec. 3701. Exemption for Telehealth Services.**

Under current law, tax incentives are provided to individuals who have a health savings account (HSA) that is coupled with a qualifying high-deductible health plan. Effective upon enactment of the CARES Act and for plan years beginning on or before December 31, 2021, section 3701 permits qualifying high-deductible health plans to cover telehealth and other remote care services that are not subject to the deductible.

Current law also permits an individual to qualify for the HSA tax credit if, in addition to coverage under a high-deductible health plan, they also have other separate coverage of a limited benefit – such as a plan covering disability, dental, vision, or long-term care services. This provision is modified to enable an individual to qualify for the HSA tax credit for a plan

covering telehealth services and other remote care, and applies to plan years beginning on or before December 31, 2021.

### **Sec. 3702. Inclusion of Certain Over-the-Counter Medical Products as Qualified Medical Expenses.**

Beginning with expenses incurred after December 31, 2019, purchases of menstrual products will be reimbursable as medical care expenses under health savings accounts, Archer medical savings accounts, health flexible spending arrangements, and health reimbursement arrangements.

### **Sec. 3703. Increasing Medicare Telehealth Flexibilities During Emergency Period.**

Section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 enacted into law on March 6, 2020 amended section 1135 of the Act to allow the Secretary to waive specific provisions of section 1834(m) of the Act related to Medicare telehealth during the COVID-19 public health emergency:

- The statutory requirement that a telehealth service originate from a rural area or rural census tract of an urban county that is designated as a health professional shortage area (except for tele-stroke services).
- The statutory requirement that a telehealth service originate from a health care site like a physician's office or a hospital and not the patient's home (except for monthly clinical assessments for patients with end stage renal disease (ESRD) receiving home dialysis and patients with a substance abuse disorder).
- The regulatory requirement that prohibits use of a telephone as the real-time interactive telecommunications system but only if the telephone has audio and video capabilities that are used for two-way, real-time interactive communication.

Instead of restricting the Secretary's waiver authority to just these provisions, section 3703 allows any of the requirements of section 1834(m) to be waived. In addition, section 102 only allowed waiver of the telehealth provisions if the patient had seen the physician or a member of the physician's practice within the last 3 years. Section 3703 eliminates that restriction.

### **Sec. 3704. Enhancing Medicare Telehealth Services for Federal Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) During Emergency Period.**

Under current Medicare law, only physicians and non-physician practitioners may be paid for furnishing services via telehealth. Section 3704 would expand that eligibility to FQHCs and RHCs during the COVID-19 public health emergency.

Only services represented by specific CPT codes designated by CMS are eligible to be paid under the telehealth benefit. FQHCs and RHCs are not paid based on CPT codes and are instead paid an all-inclusive rate. Section 3704 will only pay an FQHC or RHC under the telehealth benefit if its claim for payment includes a CPT code on the list of eligible telehealth services.

The Secretary is authorized to develop a payment rate for a telehealth service to an FQHC or RHC based on comparable rates paid under the physician fee schedule without going through notice and comment rulemaking. Costs associated with telehealth services are excluded from costs used to determine payment for FQHC and RHC services.

**Sec. 3705. Temporary Waiver of Requirement for Face-to-Face Visits Between Home Dialysis Patients and Physicians.**

A Medicare beneficiary with ESRD receiving home dialysis may elect to have monthly clinical assessments furnished via telehealth if monthly assessments were furnished face-to-face during first 3 months of receiving home dialysis and once every 3 months thereafter. Section 3705 allows the Secretary to waive the face-to-face requirement during the COVID-19 public health emergency.

**Sec. 3706. Use of Telehealth to Conduct Face-to-Face Encounter Prior to Recertification of Eligibility for Hospice Care.**

A Medicare hospice patient is required to have a face-to-face encounter with a physician or nurse practitioner to determine continued eligibility for hospice care prior to the 180th-day recertification and each subsequent recertification. Section 3706 allows the face-to-face visit to be furnished via telehealth during the COVID-19 public health emergency.

**Sec. 3707. Encouraging Use of Telecommunications Systems for Home Health Services Furnished During Emergency Period.**

Section 3707 requires the Secretary of Health and Human Services in the context of home health services covered under the Medicare program to consider ways to encourage the use of telecommunications systems, including remote patient monitoring and other communications or monitoring services consistent with the plan of care for the individual including by clarifying guidance or conducting outreach as appropriate. Remote patient monitoring means the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency.

### **Sec. 3708. Improving Care Planning for Medicare Home Health Services.**

Under current Medicare law, a physician must certify and recertify (as provided for in regulations) a patient's need for home health services. A physician must also establish and review the plan of care. Before making the certification, the physician must document that the physician him or herself, a nurse practitioner, clinical nurse specialist or nurse midwife had a face-to-face visit with the patient. Section 3708 allows these certification and care plan activities to be performed by a nurse practitioner, clinical nurse specialist working in accordance with state law or a physician assistant working under the supervision of physician.

Physicians are also prohibited from having a significant financial or contractual relationship with a home health agency for whose patients the physician is performing the above activities. This restriction is expanded to the above listed non-physician practitioners. Other provisions of statute where a requirement or restriction is limited to a physician are expanded to also include the above listed non-physician practitioners.

The above provisions apply to Medicare Part A. Identical changes are made to Medicare Part B home provisions. Conforming changes are made to the definition of "home health services," "home health agency," Medicare coverage of an osteoporosis drug furnished by a home health agency, and provisions of the home health prospective payment system. CMS has six months to complete rulemaking to implement these provisions. The rule may be interim final, if necessary, to comply with the required effective date.

### **Sec. 3709. Adjustment of Sequestration.**

The 2 percent Medicare sequester will not be applied from May 1, 2020 until December 31, 2020 and is extended otherwise through Fiscal Year 2030. The sequester would therefore end on March 31, 2031. However, for the period April 1, 2030 through September 30, 2030 the sequester would be 4 percent; it would be 0 percent from October 1, 2030 through March 31, 2031.

### **Sec. 3710. Medicare Hospital Inpatient Prospective Payment System (IPPS) Add-on Payment for COVID-19 Patients during Emergency Period.**

For discharges occurring during the COVID-19 public health emergency, section 3710 requires the Secretary to increase the final IPPS payment by 20 percent for patients diagnosed with COVID-19. Condition codes, diagnosis codes or other means can be used to identify COVID-19 patients. The Secretary is authorized to apply the same adjustment to the payment for COVID-19 patients under a Center for Medicare and Medicaid Innovation demonstration program. The increase in payment is not subject to budget neutrality and the Secretary can make the change without going through notice and comment rulemaking.

### **Sec. 3711. Increasing Access to Post-Acute Care During Emergency Period.**

*Inpatient Rehabilitation Facilities (IRF).* IRF regulations (42 CFR section 412.622) require patients in IRFs to receive 15 hours of intensive rehabilitation therapy per week. Section 3711 waives this requirement during the COVID-19 public health emergency period.

*Long Term Care Hospitals (LTCH).* LTCHs are paid either at an LTCH rate (\$42,678 on average) or a much lower site-neutral rate which is the lower of the LTCH's cost for the case or an IPPS comparable amount (\$5,801 on average). To be paid at the LTCH rate, the discharge must not be for a psychiatric or rehabilitation diagnosis and must be one of the following:

- the patient's stay in the LTCH must be immediately preceded by discharge from an acute care hospital that included at least 3 days in an intensive care unit; OR
- the patient's stay in the LTCH must be immediately preceded by discharge from an acute care hospital and the LTCH discharge must be assigned to a diagnosis related group based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH.

Section 3711 suspends the above requirements in order for LTCH cases to be paid at the LTCH rate during the COVID-19 public health emergency but only for cases admitted as a result of the public health emergency.

Under current law, at least 50 percent of LTCH discharges must be paid at the LTCH rate. If this criterion is not met, procedures are triggered that pay the LTCH under the IPPS for all of its discharges. Section 3711 does not count LTCH discharges that result from COVID-19 emergency towards the 50 percent criterion.

### **Sec. 3712. Revising Payment Rates for Durable Medical Equipment (DME) under the Medicare Program through Duration of Emergency Period.**

Medicare pays for DME on the basis of a fee schedule. Under the DME competitive bidding program which expired on December 31, 2018, CMS paid for certain DME items based on competitively bid rates. For 2019 and 2020, CMS is paying for these DME items based on the 2018 competitive bid prices updated for inflation.

*For rural areas, Alaska, Hawaii and the U.S. Territories.* Beginning June 1, 2018 through December 31, 2020, Medicare is paying for DME based on a blend of 50 percent of the historical fee schedule rates for the local area and 50 percent of rates derived from the competitive bid program. Section 3712 requires the Secretary to apply this provision of the regulation as planned for the COVID-19 public health emergency and beyond December 31, 2020 if the public health emergency is continuing at that time.

*For all other areas.* From March 6, 2020 through the remainder of the COVID-2019 public health emergency, section 3712 requires the Secretary to pay for DME based on rates that are a blend of 75 percent competitive bid program rates adjusted for inflation and 25 percent based on historical local DME fee schedule amounts

**Sec. 3713. Coverage of the COVID-19 Vaccine under Part B of the Medicare Program without any Cost-Sharing.**

Medicare provides explicit coverage for the following preventive vaccines and their administration without any cost sharing: pneumococcal, influenza and hepatitis B. (It further allows coverage of screening and preventive services rated “A” or “B” by the United States Preventive Services Task Force.) Section 3713 adds COVID-19 vaccines and their administration to the list of preventive vaccines covered by Medicare without cost sharing and does not allow Medicare Advantage (MA) plan cost sharing to exceed Medicare fee-for-service cost sharing. The provision is effective upon enactment once there is an FDA licensed vaccine available to the public.

**Sec. 3714. Requiring Medicare Prescription Drug Plans and MA-PD Plans to Allow During the COVID-19 Emergency Period for Fills and Refills of Covered Part D Drugs for Up to a 3-Month Supply.**

Subject to an exception for safety edits, effective during the COVID-19 emergency period, a Medicare Part D plan or a Medicare Advantage Prescription Drug Plan (MA-PD) is required to permit a covered individual to receive up to a 90-day supply in a single fill or refill of the total day supply prescribed. However, if a safety edit is applicable, the plan is not required to comply with the single fill or refill request.

**Sec. 3715. Providing Home and Community-Based Services in Acute Care Hospitals.**

Section 1903(h) of the Act establishes that nothing in Medicaid statute authorizes the Secretary to limit the amount of payment that can be made by a state for home and community care. Section 3715 would add specificity to that general statement so that it applies to home and community-based services under subsections (c), (d), or (i) of section 1915 and under a waiver or demonstration project, to self-directed personal assistance services (under section 1915(j)), and to home and community-based attendant services and supports (under section 1915(k)).

In addition, section 3715 adds to 1903(h) by establishing that nothing in Medicaid or Medicare statute would prohibit the receipt of any of the care or services identified above when provided in an acute care hospital so long as the care or services are:

- identified in an individual’s person-centered service plan;

- provided to meet needs of the individual that are not otherwise met through the provision of hospital services;
- not a substitute for services that the hospital is otherwise obligated to provide; and
- designed to ensure smooth transitions between acute care settings and home and community-based settings, and to preserve the individual's functional abilities.

#### **Sec. 3716. Clarification Regarding Uninsured Individuals.**

Section 6004(a) of the Families First Coronavirus Response Act (FFCRA) permits states to expand Medicaid coverage to uninsured individuals for testing for COVID-19 and related services without cost sharing. Section 3716 amends section 6004(a) of the FFCRA to permit states to provide such services to currently eligible Medicaid beneficiaries who do not under existing Medicaid coverage receive minimum essential benefits. For those individuals, state Medicaid programs may cover only a limited benefit and as a result, they may therefore be uninsured with respect to such COVID-19 testing and related services.

#### **Section 3717. Clarification Regarding Coverage of COVID-19 Testing Products.**

This amendment to section 6004 of the FFCRA alters the definition of the COVID testing that states are permitted to cover without cost sharing for Medicaid enrollees receiving coverage for COVID-19 testing and related services during the emergency period. The FFCRA authorized the coverage of in vitro diagnostic products for the detection of “SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act.” This amendment would eliminate the phrase “that are approved, cleared or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act.”

#### **Section 3718. Amendments Relating to Reporting Requirements with Respect to Clinical Diagnostic Laboratory Tests.**

Clinical diagnostic laboratories are required to report private payer rates and the volume of services paid at each rate to Medicare every 3 years. Private payer rates and volumes are then used to establish Medicare's clinical laboratory fee schedule (CLFS) payment rates. The next reporting period was scheduled to be from January 1, 2021 through March 31, 2021, but section 3718 delays it to January 1, 2022 through March 31, 2022.

CLFS payment rates were also limited to a maximum reduction of 15 percent in each year for 2021 through 2023. Section 3718 limits the reduction to 0 percent for 2021 and 15 percent in each year from 2022 through 2024.



## **Sec. 3719. Expansion of the Medicare Hospital Accelerated Payment Program During the COVID-19 Public Health Emergency.**

*Statutory Provision:* Section 1815(e)(3) of the Act provides the Secretary of Health and Human Services with authority to make accelerated payments to IPPS hospitals where unusual circumstances preclude a hospital from being unable to bill Medicare for services being provided. Section 3719 expands this authority to children's hospitals, cancer hospitals and critical access hospitals (CAH) as well as hospitals in Maryland (that may have already had this ability) during the COVID-19 public health emergency. In addition, section 3719 allows accelerated payments to cover a period of up to 6-months.

Existing provisions of regulations and the Medicare Financial Manual allow hospitals to request accelerated payment subject to approval by its Medicare Administrative Contractor (MAC) and CMS. The accelerated payment is limited to 70 percent of the amount the hospital is expected to receive. Section 3719 raises this limit to 100 percent (125 percent for CAHs). In normal circumstances, the accelerated payment provision advances payment for services being provided that cannot be billed. The 3719 provision is intended to provide payment for services hospitals have delayed or postponed as a result of the COVID-19 public health emergency.

Under the current regulatory and manual provisions, refunds of accelerated payment must be made within 90 days of payment being advanced. At that point, the MAC begins offsetting the hospital's payment for Medicare services to recoup the balance owed. Once payment is due on the 90<sup>th</sup> day, the Medicare Financial Manual requires the MAC to issue a demand letter to the hospital requesting full repayment. Interest begins accruing on any unpaid balance 30 days after the demand letter is issued. Section 3719 changes the 90 days to 120 days and allows full repayment for a period up to one-year. It does not have a provision for interest payment.

*CMS Guidance:* Section 3719 authorizes CMS to implement its provision by program instruction or otherwise. On March 28, 2020, CMS released guidance to implement this provision. The guidance goes beyond the statutory provision and allows accelerated payments for additional providers beyond those listed in the statute as well as physicians, practitioners and suppliers. For those providers not explicitly subject to the statutory provision, accelerated payment is available for 3 months of services instead of 6 months and repayment is due within 210 days of payments being accelerated. The requirement to begin offsetting the provider/supplier's Medicare payments at 120 days remains the same between the two categories of providers, practitioners and suppliers that may request accelerated payments.

CMS's guidance categorizes providers and suppliers as follows:

- *IPPS hospitals, CAHs, Children's Hospitals and Cancer Hospitals*: Advanced payment for 6 months of Part A services. Recoupment by offset beginning at 120 days. Full repayment within a year. (It is unclear whether interest is due any time within 1-year or only after 1-year).
- *Other provider types (IRFs, Inpatient Psychiatric Facilities, LTCHs, Skilled Nursing Facilities, Home Health Agencies, Hospices and Comprehensive Outpatient Rehabilitation Facilities), physicians, practitioners and other suppliers*: Advanced payment for 3 months of Part A and Part B services. Recoupment by offset beginning at 120 days. Full repayment within 210 days. (It is unclear whether interest is due any time within 210 days or only after 210 days.)

For IPPS hospitals, CAHs, children's hospitals and cancer hospitals, it is unclear whether accelerated payment for Part B services would be under the first or second category above.

To qualify for advance/accelerated payments the provider/supplier must:

1. Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form,
2. Not be in bankruptcy,
3. Not be under active medical review or program integrity investigation, and
4. Not have any outstanding delinquent Medicare overpayments.

Accelerated/Advance Payment Request forms vary by contractor and can be found on each individual MAC's website. CMS' guidance lists information for each MAC as well instructions for information to include in an accelerated payment request:

<https://www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf>.

MACs are to act on the request and advance payment within 7 calendar days of the request.

### **Section 3720. Delaying Requirements for Enhanced Federal Medical Assistance Percentage (FMAP) to Enable State Legislation Necessary for Compliance.**

Section 6008 of the FFCRA provides state and territory Medicaid programs with a temporary 6.2 percentage point increase in their regular federal matching percentage applicable to most Medicaid benefits during the emergency period so long as certain conditions are met including that the state does not impose a premium that is greater than premiums in place on January 1, 2020. (See description of those conditions above.)

Section 3720 amends section 6008 to permit states to receive the temporary FMAP increase for a period of 30 days beginning upon enactment even if premiums in place upon enactment are greater than those in effect on January 1, 2020. This would effectively provide the state with 30

days to come into compliance with this condition in order to continue receiving the temporary FMAP increase.

## **Subtitle E—Health and Human Services Extenders**

### **Part I—Medicare Provisions**

#### **Section 3801. Extend of the work geographic index floor under the Medicare program.**

Medicare’s physician fee schedule relative value units are comprised of three components: physician work, practice expense and malpractice. Each component is adjusted separately for geographic cost variation through the geographic practice cost index (GPCI). If the GPCI is more than 1.0, costs in the area are greater than the average nationwide. If the GPCI is less than 1.0, costs in the area are less than the average nationwide. Since January 1, 2004, the statute has established a floor on the physician work GPCI of 1.0. The physician work GPCI floor is set to expire on May 23, 2020. Section 3801 extends the physician work GPCI floor of 1.0 to December 1, 2020.

#### **Section 3802. Extension of funding for quality measure endorsement, input and selection.**

Under sections 1890 and 1890A of the Social Security Act, CMS enters into a contract with a consensus-based organization to assist the agency with matters relating with quality measures used for purposes of the Medicare program and other programs. The duties of the consensus-based organization include priority setting, endorsement, maintenance, and convening stakeholders to provide input on quality measures to be used under Medicare payment systems and for other purposes. Funding is derived through transfers from the Medicare Trust Funds.

The CARES Act builds on earlier extensions of this funding for fiscal year 2020 made under recent appropriations Acts to specify that \$20,000,000 is available for fiscal year 2020. For October and November 2020, an additional transfer is made for the contract in an amount equal to the pro-rated share of the \$20,000,000 fiscal year 2020 transfer. As enacted, these amounts are in addition to any remaining unobligated amounts transferred to CMS for the contract in the preceding fiscal year.

#### **Section 3803. Extension of funding outreach and assistance for low-income programs.**

Funding of transfers from the Medicare trust funds is extended for several programs providing enrollment assistance and outreach to Medicare beneficiaries. The funding levels provided for FY 2020 are the same as those in place for FY 2019. With respect to FY 2020, the amounts provided replace amounts previously legislated for the period October 1, 2019 through May 22, 2020.

- For State Health Insurance Program grants, \$13 million is provided for FY 2020, and a pro-rated share of \$13 million for October 1, 2020 through November 30, 2020.
- For Area Agencies on Aging, \$7.5 million is provided for FY 2020 and a pro-rated share of \$7.5 million is provided for October 1, 2020 through November 30, 2020.
- For Aging and Disability Resource Centers, providing outreach and assistance regarding Medicare Part D, \$5 million is provided for FY 2020 and a pro-rated share of \$5 million is provided for October 1, 2020 through November 30, 2020.
- For grants and contracts with the National Center for Benefits Outreach and Enrollment, \$12 million is provide for FY 2020 and a pro-rated share of \$12 million is provided for October 1, 2020 through November 30, 2020.

## **Part II – Medicaid Provisions**

### **Sec. 3811. Extension of the Money Follows the Person Rebalancing Demonstration Program.**

The Money Follows the Person demonstration program was initially authorized in the Deficit Reduction Act of 2005. The program, which is focused on moving Medicaid beneficiaries living in institutions to a less restrictive community setting, was initially funded through FY 2011 although subsequent laws have extended the program so that prior to the CARES Act, it would have been funded through May of 2020.

Section 3811 would replace the existing funding amount of \$176 million available for January through May of 2020 with \$337.5 million that will be available for January through September of 2020. In addition, it makes funds available for the period of October 1, 2020 through November 30, 2020. The amount made available for those two months of FY 2021 would be the pro-rata equivalent of the funds made available for the same two months of FY 2020.

### **Sec. 3812. Extension of Spousal Impoverishment Protections.**

Prior to the Affordable Care Act (ACA), states had the option of applying spousal impoverishment protections to the income of community spouses of Medicaid beneficiaries receiving home and community-based care. They were required, on the other hand, to protect the income of community spouses of Medicaid beneficiaries in a nursing home. The ACA temporarily required state Medicaid programs to apply spousal impoverishment protections to community spouses of Medicaid beneficiaries receiving home and community-based services under sections 1915(c), (d), and (i) of the Social Security Act and under demonstration waivers authorized in section 1115 of the Act. Subsequent legislation extended this requirement through May 22, 2020.

The requirement for spousal impoverishment protections for spouses of beneficiaries receiving home and community-based care is extended through November 30, 2020.

In addition, section 3812 states that nothing in the ACA provision originally requiring spousal impoverishment protections (section 2404 of P.L. 111-148) or in the relevant section of Medicaid (section 1924 of the Act) prohibits a state from:

- Applying income or resource disregards to individuals qualifying for home and community-based services or on the basis of a person's need for such services; and
- Disregarding a spouse's income and assets spent on medical care for those individuals determined to be medically needy and in need of home and community-based care. (Medically needy individuals are determined to be financially eligible for Medicaid by disregarding income spent on medical care.)

### **Sec. 3813. Delay of DSH Reductions.**

The ACA established reductions to federal allotments to states for Medicaid disproportionate share hospital (DSH) payments. Those reductions were established to reflect the reduction in the number of uninsured individuals that states would be experiencing as coverage expansions of the ACA were put into place. Initially the reductions were to begin in FY 2014 and extend through FY 2021. Subsequent legislation has delayed the implementation of the reductions so that prior to the CARES Act they were to begin in May of 2020 and extend through 2025.

Section 3813 delays the implementation of the reductions until December of 2021. For fiscal 2021, the total reduction would be decreased from \$8 billion to \$4 billion. Reductions for 2022 through 2025 are unchanged. As under prior law, no additional reductions are made in 2026 and thereafter. The reductions under the CARES Act are reflected in the table below:

<b>Fiscal Year</b>	<b>DSH Allotment Reductions under the CARES Act (\$, billions)</b>	<b>DSH Allotment Reductions under prior law (\$, billions)</b>
Beginning May 2020	0	4
2021	4 (Beginning December 2021)	8
2022	8	8
2023	8	8
2024	8	8
2025	8	8
<b>TOTAL Reductions</b>	<b>36</b>	<b>44</b>

### **Sec. 3814. Extension and Expansion of Community Mental Health Services Demonstration.**

Originally authorized in section 223 of the Protecting Access to Medicare Act of 2014, the Community Mental Health Services demonstration was authorized through FY 2016. Demonstrations were authorized to take place in 8 states. The objective of the demonstrations is to expand the scope, availability, quality of, and access to community-based mental health care. Community-based mental health care activities covered under the demonstration include crisis management services, care coordination, outpatient mental health treatment, psychiatric rehabilitation and other intensive community-based mental health services. States participating in the demonstration receive enhanced federal matching funding for the cost of mental health services provided by certified community behavioral health clinics participating in the demonstrations. The services provided by the clinics to Medicaid beneficiaries qualify for an enhanced federal matching rate that depends on the eligibility group of the beneficiary.

Subsequent legislation extended the demonstrations beyond 2016. Section 3814 further extends the demonstration through November 30, 2020. In addition, it establishes the authority for the Secretary to approve two additional states to participate. The Secretary will select two states that had previously applied to participate in the demonstration under section 223, were awarded a planning grant, but were not ultimately approved to participate. The two new participating states will not be required to submit any additional applications. The Secretary will choose the two states within six months from enactment of the CARES Act and the demonstration for those two states will extend for a period of two years. A state selected for the demonstration must submit a plan to monitor certified community behavioral health clinics to ensure compliance with demonstration criteria, collect data, and notify the Secretary of any change from the prospective payment methodology described in its demonstration application before implementing any such change.

The provision makes enhanced matching funds available for a period of 8 fiscal quarters for those states participating as demonstration states on January 1, 2020. The two new states would also be eligible for enhanced matching funds for services provided by certified community behavioral health clinics for a period of 8 fiscal quarters.

Section 3814 also requires the Government Accountability Office to provide a report, no later than 18 months after enactment, to the Committee on Energy and Commerce in the House and the Senate Finance Committee on the demonstration program under section 223. The report must address states' experiences with the demonstration, changes to access to outpatient mental health care, changes to the cost of care, and describe federal efforts to evaluate the demonstrations. The report is also required to include recommendations for improvement including on the reporting and accuracy of encounter data and the accuracy of payments to certified behavioral health clinics.

### **Part III—Human Services and Other Health Programs**

#### **Sec. 3821. Extension of Sexual Risk Avoidance Education Program.**

Funding for Sexual Risk Avoidance Education programs under section 510 of the Social Security Act is extended for the remainder of fiscal year 2020 and for the first two months of fiscal year 2021. \$75 million is provided for FY 2020 which replaces amounts previously legislated for the period October 1, 2019 through May 22, 2020. Additionally, a pro-rated share of \$75 million is provided for October 1, 2020 through November 30, 2020.

#### **Sec. 3822. Extension of Personal Responsibility Education Program.**

Funding for Personal Responsibility Education programs under section 513 of the Social Security Act is extended for the remainder of fiscal year 2020 and for the first two months of fiscal year 2021. \$75 million is provided for FY 2020 which replaces amounts previously legislated for the period October 1, 2019 through May 22, 2020. Additionally, a pro-rated share of \$75 million is provided for October 1, 2020 through November 30, 2020.

#### **Sec. 3823. Extension of Demonstration Projects to Address Health Professions Workforce Needs.**

Funding under section 2008 of the Social Security Act for the Health Professions Workforce Needs Demonstration Projects is extended through November 30, 2020. These projects are designed to help individuals obtain education and training in health care jobs that pay well and are in high demand. Section 3823 appropriates such sums as may be necessary to continue to carry out activities under these projects.

Grants and payments may be made pursuant to this authority through November 30, 2020 at a pro rata portion of \$85 million (the total amount authorized for such activities in fiscal year 2019).

#### **Sec. 3824. Extension of the Temporary Assistance for Needy Families Program and Related Programs.**

Funding for activities under part A of title IV of the Social Security Act (relating to the Temporary Assistance for Needy Families (TANF) Program), and under section 1108(b) of the Act, is extended through November 30, 2020. Section 3824 appropriates such sums as may be necessary to continue to carry out activities under these programs.



## **Part IV—Public Health Provisions**

### **Sec. 3831. Extension for Community Health Centers, the National Health Service Corps, and Teaching Health Centers that Operate GME Programs.**

Funding is provided for the remainder of fiscal year 2020 and for the first two months of fiscal year 2021 for the following programs. With respect to FY 2020, the amounts provided replace amounts previously legislated for the period October 1, 2019 through May 22, 2020.

- For the Community Health Center Fund health centers under section 330 of the PHS Act, \$4 billion for FY 2020 and \$668,493,151 for October 1, 2020 through November 30, 2020.
- For the National Health Service Corps (NHSC), \$310 million for FY 2020 and \$51,808,219 for October 1, 2020 through November 30, 2020.
- For Teaching Health Centers that Operate Graduate Medical Education Programs under section 340H of the PHS Act, \$126.5 million for FY 2020 and \$21,141,096 for October 1, 2020 through November 30, 2020.

Section 3831 applies an existing abortion restriction on the use of funds appropriated by the CARES Act to health centers, the NHSC, and teaching health centers for FY 2020 and for October 1, 2020 through November 30, 2020.

### **Sec. 3832. Diabetes Programs.**

Funding is provided for the remainder of fiscal year 2020 and for the first two months of fiscal year 2021 for the following PHS Act diabetes programs.

- Type I Diabetes, \$150 million for FY 2020 and \$25,068,493 for October 1, 2020 through November 30, 2020.
- Type II Diabetes Indian Health Service programs, \$150 million for FY 2020 and \$25,068,493 for October 1, 2020 through November 30, 2020.

## **Part V—Miscellaneous Provisions**

### **Sec. 3841. Prevention of Duplicate Appropriations for Fiscal Year 2020.**

Expenditures made under any provision of law amended by Title III of the CARES Act pursuant to amendments previously made for FY 2020 by the Continuing Appropriations Act, 2020, and

Health Extenders Act of 2019 (Public Law 116–59), the Further Continuing Appropriations Act, 2020, and Further Health Extenders Act of 2019 (Public Law 116-69), and the Further Consolidated Appropriations Act, 2020 (Public Law 23 116–94) for fiscal year 2020 shall be charged to the applicable appropriation or authorization provided by the amendments made by Title III of the CARES Act to such provision of law for such fiscal year.

#### **Subtitle F—Over-the-Counter Drugs**

This subtitle establishes an FDA user fee program for over-the-counter (OTC) drugs and provides innovative OTC drugs a period of 18 months of exclusivity. It also modifies the manner in which the FDA responds to OTC drug safety issues.

<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
<b>Families First Coronavirus Response Act Appropriations to HHS Health Programs (Titles IV and V)</b>		
<b>Office of the Secretary --Public Health and Social Services Emergency Fund</b>	<b>\$1.0 billion</b>	Funds available until expended; for activities under section 2812 of the PHS Act (pertaining to the National Disaster Medical System), in coordination with the CMS and the Assistant Secretary for Preparedness and Response, to pay claims of providers for coronavirus related items and services provided to uninsured individuals under section 6001(a) of the Families First Coronavirus Response Act (regarding testing for COVID-19). Uninsured individuals defined as those who are not enrolled in a federal health care program or a private health plan; includes uninsured individuals eligible for Medicaid for COVID-19 testing under a state option established in section 6004(a)(3) of the Families First Coronavirus Response Act.
<b>Indian Health Services (IHS)</b>	<b>\$64 million</b>	Funds available through FY 2022 for health services consisting of coronavirus related items and services (specified in section 6007). Amounts to be allocated at the discretion of the HIS Director of the IHS.
<b>CARES Act Appropriations to HHS Health Programs (Title VIII)</b>		
<b>Office of the Secretary --Public Health and Social Services Emergency Fund</b>		<p>As described in the rows immediately below, a total of \$127.3 billion is appropriated to the fund for three major purposes: assisting health care providers with expenses and lost revenue due to coronavirus; development and purchase of vaccines and other specified preparedness and response activities.</p> <p>The funds may be used to restore amounts, directly or through reimbursements, for obligations incurred to prevent, prepare for, and respond to coronavirus prior to enactment of the CARES Act.</p> <p>For purposes of any funding provided to the Health Centers Program (section 330 of the PHS Act) for FY 2020, funding for maintaining or increasing health center capacity and staffing levels during the coronavirus public health emergency is deemed a cost of prevention, diagnosis and treatment of coronavirus.</p>
<b>Office of the Secretary --Public</b>	<b>\$100 billion</b>	Amount to remain available until expended for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that

<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
Health and Social Services Emergency Fund		<p>are attributable to coronavirus.</p> <p>Eligible health care providers are public entities, Medicare or Medicaid enrolled suppliers and providers, and such other for-profit and nonprofit entities as the Secretary may specify, within the US (including territories), that provide diagnoses, testing, or care for individuals with possible or actual cases of COVID-19.</p> <p>Funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. Recipients must submit reports and maintain documentation as the Secretary requires to ensure compliance with conditions imposed for these payments.</p> <p>Eligible health care providers must submit an application that includes a statement justifying the provider's need for the payment and the provider must have a valid tax identification number.</p> <p>Applications to be reviewed and payments made on a rolling basis. Payments may include a pre-payment, prospective payment, or retrospective payment, as determined appropriate by the Secretary. Payments are to be made in consideration of the most efficient payment systems practicable to provide emergency payment.</p> <p>Funds may be used for building or construction of temporary structures, leasing of properties, medical supplies and equipment including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity.</p> <p>The Secretary is to report to the House and Senate appropriations committees within 60 days of enactment and every 60 days thereafter on the obligation of funds, including by state, until funds are expended. Within 3 years after the final payments are made, the HHS Inspector General (IG) must issue a final report on audit findings for this program to the House and Senate appropriations committees. The IG may conduct audits of interim payments at an earlier date.</p>

Appropriations to HHS Health Programs – Families First and CARES Acts		
Agency	Amount	Purposes
Office of the Secretary --Public Health and Social Services Emergency Fund	\$27.0145 billion	<p>Funds available through FY 24 to prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities. Funds may be used to develop and demonstrate innovations and enhancements to manufacturing platforms.</p> <p>Secretary is directed to purchase coronavirus vaccines in quantities determined adequate to address the public need. All purchases to be made using federal guidance on fair and reasonable pricing and Secretary to use current authority to ensure vaccines, therapeutics, and diagnostics developed from these funds will be affordable in the commercial market, without delaying the development of such products. Products purchased with these funds may be deposited in the Strategic National Stockpile. Up to \$16 billion of the funds may be used for this purpose and merged with the Covered Countermeasure Process Fund.</p> <p>Funds may be used to reimburse the Veterans Health Administration to prevent, prepare for and respond to coronavirus and to provide medical care for these purposes to individuals not eligible for veterans health services, if the Secretary of HHS certifies to the appropriations committees that funds available for assignment under the Disaster Relief Act of 1974 (PL 93-288) are insufficient and these funds are needed to reimburse the Department of Veterans Affairs for expenses incurred in providing health care to civilians.</p> <p>Funds may be used for grants for the construction, alteration, or renovation of non-federally owned facilities (1) to improve preparedness and response capability at the state and local level, and (2) for the production of vaccines, therapeutics, and diagnostics where the Secretary determines such a contact is needed to ensure enough supplies.</p>

<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
<b>Allocations specified within the \$27 billion total:</b>		
	≥\$250 million	For grants or cooperative agreements with entities that are grantees or sub-grantees of the Hospital Preparedness Program (section 319C-2 of the PHS Act) or that meet other criteria of the Secretary and awarded under that program or section 311 of the PHS Act (pertaining to federal-state cooperation with respect to quarantines and prevention and suppression of communicable diseases).
	≥\$3.5 billion	Biomedical Advanced Research and Development Authority (BARDA) for manufacturing, production, and purchase of vaccines, therapeutics, diagnostics and small molecule active pharmaceutical ingredients including the development translation and demonstration at scale of innovative manufacturing platforms. These funds may be used for construction or renovation of non-federal US-based next generation manufacturing facilities.
	≤\$289 million	May be transferred as needed to other federal agencies for expenses related to medical care for persons eligible for treatment pursuant to section 322 of the PHS Act (pertaining to persons under quarantine).
	\$1.5 million	Available for agreement, within 60 days of enactment, with the National Academies of Sciences Engineering and Medicine to examine and report on security of US medical product supply chains.
<b>Office of the Secretary --Public Health and Social Services Emergency Fund</b>	<b>\$275 million</b>	Available through FY 2022 to prevent, prepare for, and respond to coronavirus, domestically or internationally.  PHS Act provisions regarding required funding for core medical services do not apply to these funds.
<b>Allocations specified within the \$275 million total:</b>		
	\$90 million	For Ryan White HIV/AIDs Programs, to modify existing contracts and supplements to existing grants and cooperative agreements to respond to coronavirus domestically or internationally. These supplements are to be awarded using a data-driven methodology determined by the Secretary.
	\$5 million	For HRSA Health Care Systems, for improving the capacity of poison control centers.
	\$180 million	For HRSA Rural Health to carry out telehealth and rural health activities under sections 330A and 330I of the PHS Act and sections 711 (the Office of Rural Health Policy) and 1820 (Medicare Rural Hospital Flexibility Program) of the Social Security Act to prevent, prepare for and respond to

<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
		coronavirus domestically or internationally. Of this amount \$15 million must be allocated to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes. Sections 1820(g)(3)(A), (g)(3)(D), and (g)(3)(E) do not apply; these pertain to specific uses of funds and impose a \$50,000 limit on grants under the Medicare Rural Hospital Flexibility Program.
<b>Centers for Disease Control and Prevention (CDC)</b>	<b>\$4.3 billion</b>	<p>For CDC-wide activities and program support; available through FY 24 to prevent, prepare for, and respond to coronavirus domestically and internationally.</p> <p>CDC directed to report to the House and Senate Appropriations committees on the development of a public health surveillance and data collection system for coronavirus within 30 days of enactment of the CARES Act.</p> <p>Funds may be used for grants for the rent, lease, purchase, acquisition, construction, alteration, or renovation of non-federally owned facilities to improve state and local preparedness and response capability. Funds may also be used for purchase and insurance of official vehicles in foreign countries.</p>
<b>Allocations specified within the \$4.3 billion total:</b>		
	≥\$1.5 billion	For State and Local Preparedness Grants: for states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes, including to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. Every grantee that received a Public Health Emergency Preparedness grant for FY 2019 to receive at least the same amount from these funds. At least \$125 million to be allocated to tribal organizations, urban Indian health organizations, or health service providers to tribes. Funding may be provided through other grant or cooperative agreement mechanisms.
	≥\$0.5 billion	For global disease detection and emergency response
	≥\$0.5 billion	For public health data surveillance and analytics infrastructure modernization.
	\$0.3 billion	Transferred to the Infectious Diseases Rapid Response Reserve Fund established by section 231 of division B of P.L. 115–245. HHS to report every 14 days to the Senate and House appropriations committees for one year on commitments and obligations of the Reserve Fund after an infectious



<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
		disease emergency is declared as a public health emergency or is determined by the Secretary to have significant potential to be imminent and, on occurrence, to affect the health and security of US citizens domestically or internationally.
<b>National Institutes of Health (NIH)</b>		A total of \$945.4 million appropriated to various Institutes to be made available through FY 24 to prevent, prepare for, and respond to coronavirus domestically and internationally.
<b>Appropriations specified:</b>		
	\$103.4 million	National Heart, Lung, and Blood Institute
	\$706 million	National Institute of Allergy and Infectious Diseases. Of this amount, at least \$156 million to be provided for the study of, construction of, demolition of, renovation of, and acquisition of equipment for vaccine and infectious diseases research facilities of or used by NIH, including the acquisition of real property.
	\$60 million	National Institute of Biomedical Imaging and Bioengineering
	\$10 million	National Library of Medicine.
	\$36 million	National Center for Advancing Translational Sciences
	\$30 million	Office of the Director
<b>Substance Abuse and Mental Health Services Administration (SAMSHA)</b>	<b>\$425 million</b>	For Health Surveillance and Program Support; to remain available through FY 2021, to prevent, prepare for, and respond to coronavirus, domestically or internationally.
<b>Allocations specified within the \$425 million total:</b>		
	≥\$250 million	For the Certified Community Behavioral Health Clinic Expansion Grant program
	≥\$100 million	For SAMSHA Emergency Response Grants (section 501(o) of the PHS Act)
	≥\$50 million	For suicide prevention programs
	≥\$15 million	To be allocated to tribes, tribal organizations, urban Indian health organizations, or health or behavioral health service providers to tribes

<b>Appropriations to HHS Health Programs – Families First and CARES Acts</b>		
<b>Agency</b>	<b>Amount</b>	<b>Purposes</b>
<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>	<b>\$200 million</b>	<p>For Program Management; to remain available through FY 2023 to prevent, prepare for and respond to coronavirus, domestically or internationally.</p> <p>At least \$100 million to be available for the survey and certification program, prioritizing nursing home facilities in localities with community transmission of coronavirus.</p>